

Printing date 29.06.2023 Version number 2 Revision: 29.06.2023

1 Identification of the substance or mixture and of the supplier

- · Product identifier
- Trade name: IPS e.max ZirCAD Colouring Liquid Diluter
- Relevant identified uses of the substance or mixture and uses advised against No further relevant information available.
- · Application of the substance / the mixture

Manufacture of dental prothesis

Colouring Liquid

- · Details of the supplier of the safety data sheet
- · Manufacturer/Supplier:

Ivoclar Vivadent AG

Bendererstrasse 2

9494 Schaan

PRINCIPALITY OF LIECHTENSTEIN

Tel: +423 235 35 35 / Fax: +423 235 33 60

Importer:

Ivoclar Vivadent Ltd.

12 Omega St, Rosedale, Auckland

New Zealand

Tel: + 64 9 914 9999 / Fax: + 64 9 914 9990

· Further information obtainable from:

Regulatory Affairs

sds@ivoclarvivadent.com

· Emergency telephone number: 0800 764 766 (National Poison Centre - 24 hours / 7 days)

2 Hazards identification

Classification of the substance or mixture

The product is not classified, according to the Globally Harmonised System (GHS).

- · Label elements
- · GHS label elements Void
- · Hazard pictograms Void
- · Signal word Void
- · Hazard statements Void
- · Other hazards
- · Results of PBT and vPvB assessment
- · **PBT:** Not applicable.
- · vPvB: Not applicable.

3 Composition/Information on ingredients

- · Chemical characterisation: Mixtures
- · **Description:** Mixture of substances listed below with nonhazardous additions.
- · Dangerous components: Void
- · Additional information: For the wording of the listed hazard phrases refer to section 16.

4 First aid measures

· General information: No special measures required.

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· After inhalation:

Supply fresh air or oxygen; call for doctor.

In case of unconsciousness place patient stably in side position for transportation.

- · After skin contact: Rinse with water.
- · After eye contact: Rinse opened eye for several minutes under running water. Then consult a doctor.
- · After swallowing: Rinse out mouth and then drink plenty of water.
- · Information for doctor:
- · Most important symptoms and effects, both acute and delayed No further relevant information available.
- Indication of any immediate medical attention and special treatment needed No further relevant information available.

5 Fire fighting measures

· Suitable extinguishing agents:

The product is not flammable.

Use fire extinguishing methods suitable to surrounding conditions.

- · Special hazards arising from the substance or mixture No further relevant information available.
- · Protective equipment: No special measures required.

6 Accidental release measures

- · Personal precautions, protective equipment and emergency procedures Wear protective clothing.
- · Environmental precautions: Dilute with plenty of water.
- · Methods and material for containment and cleaning up:

Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).

· Reference to other sections

See Section 7 for information on safe handling.

See Section 8 for information on personal protection equipment.

See Section 13 for disposal information.

7 Handling and storage

- · Handling:
- · Precautions for safe handling

Only adequately trained personnel should handle this product.

For use in dentistry only.

- · Information about fire and explosion protection: No special measures required.
- · Storage:
- Requirements to be met by storerooms and receptacles: Store only in the original receptacle.
- · Information about storage in one common storage facility: Not required.
- · Further information about storage conditions: None.
- · Specific end use(s) No further relevant information available.

8 Exposure controls/personal protection

- · Additional information about design of technical facilities: No further data; see item 7.
- · Ingredients with limit values that require monitoring at the workplace:

The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.

· Additional information: The lists valid during the making were used as basis.

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- · Personal protective equipment:
- General protective and hygienic measures:

Usual hygienic measures for dental practice and dental laboratories.

Keep away from foodstuffs, beverages and feed. Wash hands before breaks and at the end of work.

- · Respiratory protection: Not required.
- · Protection of hands:



Protective gloves (EN 374)

After use of gloves apply skin-cleaning agents and skin cosmetics.

· Material of gloves

Natural rubber, NR

Chloroprene rubber, CR

Nitrile rubber, NBR

Butyl rubber, BR

Fluorocarbon rubber (Viton)

· Penetration time of glove material

The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.

· Eye protection:



Tightly sealed goggles (EN 166)

9 Physical and chemical properties

· General Information

· Appearance:

· Form: Fluid · Colour: Colourless **Odourless** · Odour: Not determined. · Odour threshold:

· pH-value at 20 °C: 2.1

· Change in condition

Undetermined. · Melting point/freezing point: · Initial boiling point and boiling range: 100 °C · Flash point: Not applicable.

· Flammability (solid, gas): Not applicable.

· Auto-ignition temperature: Product is not selfigniting.

· Explosive properties: Product does not present an explosion hazard.

· Vapour pressure at 20 °C: 23 hPa · Density at 20 °C: $1 g/cm^3$ · Relative density

Not determined. · Vapour density Not determined. · Evaporation rate Not determined.

· Solubility in / Miscibility with

Fully miscible. · Partition coefficient: n-octanol/water: Not determined.

· Viscosity:

Dynamic: Not determined.

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· Kinematic:	Not determined.
· Other information	No further relevant information available.

10 Stability and reactivity

- · Reactivity No further relevant information available.
- · Chemical stability Stable under normal handling and storage conditions.
- Thermal decomposition / conditions to be avoided: No decomposition if used according to specifications.
- · Possibility of hazardous reactions No dangerous reactions known.
- · Conditions to avoid No further relevant information available.
- · Incompatible materials: No further relevant information available.
- · Hazardous decomposition products: None under normal conditions of storage and use.

11 Toxicological information

- · Information on toxicological effects
- · Acute toxicity Based on available data, the classification criteria are not met.
- · Skin corrosion/irritation Based on available data, the classification criteria are not met.
- · Serious eye damage/irritation Based on available data, the classification criteria are not met.
- Respiratory or skin sensitisation Based on available data, the classification criteria are not met.
- · Germ cell mutagenicity Based on available data, the classification criteria are not met.
- · Carcinogenicity Based on available data, the classification criteria are not met.
- · Reproductive toxicity Based on available data, the classification criteria are not met.
- · STOT-single exposure Based on available data, the classification criteria are not met.
- · STOT-repeated exposure Based on available data, the classification criteria are not met.
- · Aspiration hazard Based on available data, the classification criteria are not met.

12 Ecological information

- · Toxicity
- · Aquatic toxicity: No further relevant information available.
- · Persistence and degradability No further relevant information available.
- · Behaviour in environmental systems:
- · Bioaccumulative potential No further relevant information available.
- · Mobility in soil No further relevant information available.
- Additional ecological information:
- · General notes: Not hazardous for water.
- · Results of PBT and vPvB assessment
- · **PBT:** Not applicable.
- · vPvB: Not applicable.
- · Other adverse effects No further relevant information available.

13 Disposal considerations

- · Waste treatment methods
- · Recommendation Disposal must be made according to official regulations.

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- · Uncleaned packaging:
- · **Recommendation:** Disposal must be made according to official regulations.

Transport information	
UN-Number NZS/RID/ADN, ADN, IMDG, IATA	Void
UN proper shipping name NZS/RID/ADN, ADN, IMDG, IATA	Void
Transport hazard class(es)	
NZS/RID/ADN, ADN, IMDG, IATA Class	Void
Packing group NZS/RID/ADN, IMDG, IATA	Void
Environmental hazards:	Not applicable.
Special precautions for user	Not applicable.
Transport in bulk according to Annex II of and the IBC Code	Marpol Not applicable.
Transport/Additional information:	Product is not classified as a dangerous good for transport (ADR, IMDG, IATA).
UN "Model Regulation":	Void

15 Regulatory information

- · Safety, health and environmental regulations/legislation specific for the substance or mixture
- · New Zealand Inventory of Chemicals

All ingredients are listed.

- · GHS label elements Void
- · Hazard pictograms Void
- · Signal word Void
- · Hazard statements Void
- · Directive 2012/18/EU
- · Named dangerous substances ANNEX I None of the ingredients is listed.
- · National regulations:
- · Other regulations, limitations and prohibitive regulations

The product is a medical device according to Regulation 2017/745 on Medical Devices (MDR).

· Chemical safety assessment: A Chemical Safety Assessment has not been carried out.

16 Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

- · Contact:
- · Abbreviations and acronyms:

ADR: Accord relatif au transport international des marchandises dangereuses par route (European Agreement Concerning the International Carriage of Dangerous Goods by Road)

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IMDG: International Maritime Code for Dangerous Goods IATA: International Air Transport Association

EINECS: European Inventory of Existing Commercial Chemical Substances

ELINCS: European List of Notified Chemical Substances
CAS: Chemical Abstracts Service (division of the American Chemical Society)
PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative